

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Investigating the effect of motivational interviewing on lifestyle affecting weight, body mass index and weight changes in overweight and obese women with polycystic ovary syndrome

Protocol summary

Study aim

Determining the effect of motivational interviewing on lifestyle changes and body mass index in overweight and obese women with polycystic ovary syndrome

Design

A clinical trial with a control group, with parallel groups, randomized by simple random method, sample size:60 patients.

Settings and conduct

The study is conducted on two groups of patients with polycystic ovary syndrome, one group receives an intervention (motivational interview) in five weekly sessions, and the control group receives a lifestyle booklet. The place of the study is Shahid Rezaei specialized clinic in Lande city, located in Kohgiluyeh and Boyer Ahmad province

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with polycystic ovary syndrome according to the diagnosis of the attending physician based on the Rotterdam criteria, having the desire and informed consent to participate in the research.

Exclusion criteria: being pregnant or undergoing fertility treatment, the presence of chronic diseases such as diabetes, cardiovascular, smoking, drugs and alcohol according to the patient

Intervention groups

Intervention group: overweight and obese women with polycystic ovary syndrome who will be given a motivational interview and the control group will receive a healthy lifestyle booklet.

Main outcome variables

Average body mass index; Average lifestyle score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231121060125N1**

Registration date: **2023-12-25, 1402/10/04**

Registration timing: **prospective**

Last update: **2023-12-25, 1402/10/04**

Update count: **0**

Registration date

2023-12-25, 1402/10/04

Registrant information

Name

Fereshteh Khaleghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 74 3246 3133

Email address

f.khaleghi@stu.ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-08-21, 1403/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of motivational interviewing on lifestyle affecting weight, body mass index and weight

changes in overweight and obese women with polycystic ovary syndrome	
Public title	Investigating the effect of motivational interviewing on lifestyle affecting weight, body mass index and weight changes in overweight and obese women with polycystic ovary syndrome
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Women with polycystic ovary syndrome according to the rotterdam criteria Informed concept Body mass index more than 25 Kg/m2 At least literate in reading and writing and speaking Persian language Iranian and resident of Lande city Ages 15 to 45 years Having a mobile phone Exclusion criteria: Being pregnant or undergoing fertility treatment Having chronic diseases such as diabetes, cardiovascular disease, etc. The presence of various types of severe mental disorders (psychosis, etc.) Restrictions on physical activity Having diseases that require following a special diet Existence of stressful events during the past 6 months, such as migration, divorce, financial problems, etc. Smoking, drugs and alcohol
Age	No age limit
Gender	Female
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization is done individually using a table of random numbers, and the participants are assigned to two intervention and control groups. After dividing, people will complete the study questions (demographic information questionnaire and lifestyle questionnaire). The intervention group will conduct 5 motivational interview sessions at the gynecology clinic affiliated to Yasouj University of Medical Sciences, and the control group will receive lifestyle modification booklets in polycystic ovary syndrome.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Other
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Shahid Sadougi University of Medical Sciences, Yazd
Street address	Shahid Bahonar square
City	Yazd
Province	Yazd
Postal code	8915818411
Approval date	2023-11-04, 1402/08/13
Ethics committee reference number	IR.SSU.REC.1402.062
Health conditions studied	
1	
Description of health condition studied	Polycystic ovary syndrome
ICD-10 code	E28.2
ICD-10 code description	Polycystic ovarian syndrome
Primary outcomes	
1	
Description	Average body mass index of obese women with polycystic ovary syndrome
Timepoint	The time of starting the study and one month after the intervention
Method of measurement	kg/m2
2	
Description	Average lifestyle score of obese women with polycystic ovary syndrome
Timepoint	At the beginning of the study, two months later
Method of measurement	Questionnaire
Secondary outcomes	
1	
Description	Quality life
Timepoint	

Two months after starting the study

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: overweight and obese women with polycystic ovary syndrome

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rezaei specialized clinic in Lende city

Full name of responsible person

Afsaneh Azadeh

Street address

Shahid Motahari

City

Lende

Province

Kohgiluyeh-va-Boyer-Ahmad

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7574144798

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a.azadeh.1372@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi

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Shahid Bahonar

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Province

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8916188637

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Behnaz Enjezab

Position

Assistant Professor

Latest degree

Ph.D.

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Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available